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Date of Deposit: June 25, 2003

PATENT
CASE NO. 6298/432

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
George Baran)
Serial No. To be Assigned)
Filed: Herewith)
For: NEBULIZING CATHETER)
SYSTEM AND METHODS OF)
USE AND MANUFACTURE)

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to the obligation under 37 C.F.R. § 1.56 and in conformance with 37 C.F.R. § 1.97-1.99, Applicant hereby submits the following list of references for consideration by the Examiner.

All of the references listed below and on the enclosed PTO-1449 were previously cited by the Examiner or submitted by Applicant in prior Application Serial Nos. 09/265,603, 08/787,913, and 08/261,866 to which Applicant claims priority under 35 U.S.C. § 120. Accordingly, copies of these previously cited or submitted references are not provided in this Information Disclosure Statement as permitted by 37 C.F.R. § 1.98(d).

U.S. PATENTS

Document No.	Date	Inventor
829,952	09/04/1906	W. M. Dean
852,154	04/30/1907	M. Bariffi
2,638,096	05/12/1953	E. A. Waldhaus
3,788,326	01/29/1974	Jacobs
3,144,868	08/18/1964	M. E. Jascalevich
4,270,530	6/1981	Baum et al.
4,319,115	3/1982	Nakai et al.
4,327,721	05/04/1982	Goldin et al.
4,488,548	12/18/1984	Agdanowski
4,584,998	4/1986	McGrail
4,622,968	11/18/1986	Persson
4,646,733	03/03/1987	Stroh et al.
4,655,746	4/1987	Daniels et al.
4,661,110	04/28/1987	Fortier et al.
4,669,463	6/1987	McConnell
4,690,138	09/01/1987	Heyden
4,739,756	4/1988	Horn
4,805,609	02/21/1989	Roberts et al.
4,819,664	4/1989	Nazari
4,821,714	4/1989	Smelser
4,829,996	5/1989	Noakes et al.
4,832,012	5/1989	Raabe et al.
4,840,172	06/20/1989	Augustine et al.
4,881,542	11/21/1989	Schmidt et al.
4,886,055	12/12/1989	Hoppough
4,945,929	8/1990	Egilmex
4,955,375	9/1990	Martinez
5,012,804	5/7/1991	Foley et al.
5,025,806	6/1991	Palmer et al.
5,029,580	07/09/1991	Radford et al.
5,031,613	7/1991	Smith et al.
5,049,137	9/1991	Thompson
5,060,646	10/1991	Page
5,062,423	11/1991	Matson et al.
5,072,726	12/17/1991	Mazloomdoost et al.
5,078,131	1/1992	Foley
5,115,971	5/1992	Greenspan et al.
5,116,088	5/26/1992	Bird
5,119,807	06/09/1992	Roberts
5,125,893	6/1992	Dryden
5,146,916	9/1992	Catalani
5,152,277	10/06/1992	Honda et al.
5,158,536	10/1992	Sekins et al.
5,167,622	12/1992	Muto
5,178,138	01/12/1993	Walstrom et al.

Document No.	Date	Inventor
5,186,166	2/1993	Riggs et al.
5,193,533	03/16/1993	Body et al.
5,197,463	03/30/1993	Jeshuran
5,207,220	5/1993	Long
5,217,005	06/08/1993	Weinstein
5,231,983	8/1993	Matson et al.
5,233,979	8/1993	Strickland
5,255,675	10/26/1993	Kolobow
5,261,892	11/16/1993	Bertaud et al.
5,285,778	02/15/1994	Mackin
5,287,847	02/22/1994	Piper et al.
5,287,849	2/1994	Piper et al.
5,287,850	02/22/1994	Haber et al.
5,291,882	3/1994	Makhoul et al.
5,313,939	05/24/1994	Gonzalez
5,329,921	07/19/1994	Socaris et al.
5,333,607	08/02/1994	Kee et al.
5,372,131	12/13/1994	Heinen Jr.
5,433,195	07/18/1995	Kee et al.
5,438,982	08/08/95	MacIntyre
5,443,447	08/22/95	Kassis
5,480,380	01/02/1996	Martin
5,499,625	03/19/1996	Frass et al.
5,515,844	05/14/1996	Christopher
5,606,968	03/04/1997	Mang
5,611,336	03/18/1997	Page et al.
5,642,730	07/01/1997	Baran
5,803,078	09/08/1998	Brauner
5,964,223	10/12/1999	Baran
6,079,413	06/27/2000	Baran
6,082,361	07/04/2000	Morejon
6,086,529	07/11/2000	Arndt
6,102,042	08/15/2000	Hete et al.
6,237,597 B1	05/29/2001	Kovac
6,257,236 B1	07/10/2001	Dutkiewicz

FOREIGN DOCUMENTS

Document No.	Date	Country
0 180 038 A1	09/1985	Europe
0 289 336 A2	2/1988	Europe
0 445 502	09/1991	Europe
0 453 234	10/1991	Europe
0 487 155	05/1992	Europe
0 587 380 A1	3/1994	Europe

Document No.	Date	Country
0 587 380	3/1994	Europe
2 569 114	8/1984	France
WO 87/05522	9/1987	PCT
WO 89/05670	06/1989	PCT
WO 90/07951	07/1990	PCT
WO 93/17744	09/1993	PCT
WO 95/30448	11/1995	PCT
GB 2 098 485	05/1984	Great Britain
GB 2 268 286	09/1992	Great Britain
185442	08/1966	Russia (USSR)
812296	03/1981	Russia (USSR)

OTHER ART

Hoover et al., "A Microspray Nozzle for Local Administration of Liquids or Suspensions to Lung Airways via Bronchoscopy," *Journal of Aerosol Medicine*, vol. 6, #2, 1993.

Wheeldon et al., *Aerosolized Endotoxin in Animals*, (1992).

Carlton, Graziano C.; Barker, Robert L.; Benua, Richard S.; Guy, Yvonne G; Airway Humidification With High-Frequency Jet Ventilation, *Critical Care Medicine*, vol. 13, No. 2, (1985).

Aiache, Jean-Marc; The Ideal Drug Delivery System: A Look into the Future, *Journal of Aerosol Medicine*, vol. 4, No. 4, 1991.

Wheeldon, Walker, Murphy, and Turner; *Aerosolized Endotoxin in Animals*, (1992).

Jager-Waldau, Reinhold; A Two-Phase-Flow Mechanical Spray Pump: A Possible Alternative To Propellant-Driven MDIs. *Journal of Biopharmaceutical Sciences*, 3(1/2), 077-084, (1992).

Niven, Ralph W.; Kacmarek, Robert M.; Brain, Joseph D.; Peterfreund, Robert A.; Small Bore Nozzle Extensions to Improve the Delivery Efficiency of Drugs from Metered Dose Inhalers: Laboratory Evaluation. *Am Rev Respir Dis*, vol. 147. pp. 1590-1594, 1993.

Taylor, Robert H.; Lerman, Jerrold; Chambers, Carole; Dolovich, Myrna; Dosing Efficiency and Particle-Size Characteristics of Pressurized Metered-Dose Inhaler Aerosols in Narrow Catheters. Presented at Annual Meeting American Society of Anesthesiologist, Las Vegas, Oct. 1990.

Hess, Dean; Inhaled Bronchodilators During Medical Ventilation: Delivery Techniques, Evaluation of Response, and Cost Effectiveness, *Respiratory Care*, vol. 39 No. 2, Feb. 1994.

Judson, Marc A.; Sahan, Steven A.; Mobilization of Secretions in ICU Patients, *Respiratory Care*, vol. 39 No. 3, Mar. 1994.

Copy of packaging for "ENDO-JET by Autovage", believed to have been published prior to June 14, 1994, 2 pages.

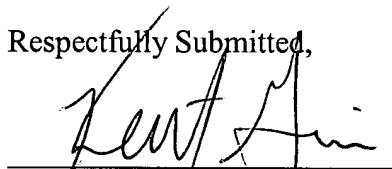
Copy of packaging for "EMT Emergency Medicine Tube", by Mallinckrodt Medical, dated January 1993, 4 pages.

EXPLANATION OF THE REFERENCES

As of the day of filing of this information disclosure statement, a first office action on the merits has not been received by the undersigned. Accordingly, no fee for consideration of the information provided with this disclosure statement is included herewith, as permitted by 37 C.F.R. § 1.97(b)(3). However, if an office action on the merits is mailed on a date prior hereto, Applicant hereby requests and authorizes the Commissioner to charge Deposit Account 23-1925 for the appropriate fee of \$180 as set forth in 37 C.F.R. § 1.97(c) for consideration of the information set forth in this disclosure statement.

Applicant requests to have these references included in the record of this application. Applicant further requests that the Examiner review the entire disclosure of each reference. Applicant does not represent any of these references to be prior art and Applicant reserves the right to disqualify any references by the showing of an earlier date of invention, if appropriate.

Respectfully Submitted,



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FORM PTO-1449	SERIAL NO. To be Assigned	CASE NO. 6298/432
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT	FILING DATE Herewith	GROUP ART UNIT
(use several sheets if necessary)	APPLICANT(S): George Baran	

REFERENCE DESIGNATION **U.S. PATENT DOCUMENTS**

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS/ SUBCLASS	FILING DATE
	A1 829,952	09/04/1906	W. M. Dean		
	A2 852,154	04/30/1907	M. Bariffi		
	A3 2,638,096	05/12/1953	E. A. Waldhaus		
	A4 3,788,326	01/29/1974	Jacobs		
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	A6 4,270,530	6/1981	Baum et al.		
	A7 4,319,115	3/1982	Nakai et al.		
	A8 4,327,721	05/04/1982	Goldin et al.		
	A9 4,488,548	12/18/1984	Agdanowski		
	A10 4,584,998	4/1986	McGrail		
	A11 4,622,968	11/18/1986	Persson		
	A12 4,646,733	03/03/1987	Stroh et al.		
	A13 4,655,746	4/1987	Daniels et al.		
	A14 4,661,110	04/28/1987	Fortier et al.		
	A15 4,669,463	6/1987	McConnell		
	A16 4,690,138	09/01/1987	Heyden		
	A17 4,739,756	4/1988	Horn		
	A18 4,805,609	02/21/1989	Roberts et al.		
	A19 4,819,664	4/1989	Nazari		
	A20 4,821,714	4/1989	Smelser		
	A21 4,829,996	5/1989	Noakes et al.		
	A22 4,832,012	5/1989	Raabe et al.		
	A23 4,840,172	06/20/1989	Augustine et al.		
	A24 4,881,542	11/21/1989	Schmidt et al.		
	A25 4,886,055	12/12/1989	Hoppough		
	A26 4,945,929	8/1990	Egilmex		
	A27 4,955,375	9/1990	Martinez		
	A28 5,012,804	5/7/1991	Foley et al.		
	A29 5,025,806	6/1991	Palmer et al.		
	A30 5,029,580	07/09/1991	Radford et al.		
	A31 5,031,613	7/1991	Smith et al.		
	A32 5,049,137	9/1991	Thompson		
	A33 5,060,646	10/1991	Page		

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609;
Draw line through citation if not in conformance and not considered. Include copy of this form with next
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	A34 5,062,423	11/1991	Matson et al.		
	A35 5,072,726	12/17/1991	Mazloomdoost et al.		
	A36 5,078,131	1/1992	Foley		
	A37 5,115,971	5/1992	Greenspan et al.		
	A38 5,116,088	5/26/1992	Bird		
	A39 5,119,807	06/09/1992	Roberts		
	A40 5,125,893	6/1992	Dryden		
	A41 5,146,916	9/1992	Catalani		
	A42 5,152,277	10/06/1992	Honda et al.		
	A43 5,158,536	10/1992	Sekins et al.		
	A44 5,167,622	12/1992	Muto		
	A45 5,178,138	01/12/1993	Walstrom et al.		
	A46 5,186,166	2/1993	Riggs et al.		
	A47 5,193,533	03/16/1993	Body et al.		
	A48 5,197,463	03/30/1993	Jeshuran		
	A49 5,207,220	5/1993	Long		
	A50 5,217,005	06/08/1993	Weinstein		
	A51 5,231,983	8/1993	Matson et al.		
	A52 5,233,979	8/1993	Strickland		
	A53 5,255,675	10/26/1993	Kolobow		
	A54 5,261,892	11/16/1993	Bertaud et al.		
	A55 5,285,778	02/15/1994	Mackin		
	A56 5,287,847	02/22/1994	Piper et al.		
	A57 5,287,849	2/1994	Piper et al.		
	A58 5,287,850	02/22/1994	Haber et al.		
	A59 5,291,882	3/1994	Makhoul et al.		
	A60 5,313,939	05/24/1994	Gonzalez		
	A61 5,329,921	07/19/1994	Socaris et al.		
	A62 5,333,607	08/02/1994	Kee et al.		
	A63 5,372,131	12/13/1994	Heinen Jr.		
	A64 5,433,195	07/18/1995	Kee et al.		
	A65 5,438,982	08/08/95	MacIntyre		

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	A66 5,443,447	08/22/95	Kassis		
	A67 5,480,380	01/02/1996	Martin		
	A68 5,499,625	03/19/1996	Frass et al.		
	A69 5,515,844	05/14/1996	Christopher		
	A70 5,606,968	03/04/1997	Mang		
	A71 5,611,336	03/18/1997	Page et al.		
	A72 5,642,730	07/01/1997	Baran		
	A73 5,803,078	09/08/1998	Brauner		
	A74 5,964,223	10/12/1999	Baran		
	A75 6,079,413	06/27/2000	Baran		
	A76 6,082,361	07/04/2000	Morejon		
	A77 6,086,529	07/11/2000	Arndt		
	A78 6,102,042	08/15/2000	Hete et al.		
	A79 6,237,597 B1	05/29/2001	Kovac		
	A80 6,257,236 B1	07/10/2001	Dutkiewicz		

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS/ SUBCLASS	TRANSLATION YES NO
	A81 0 180 038 A1	09/1985	Europe		
	A82 0 289 336 A2	2/1988	Europe		
	A83 0 445 502	09/1991	Europe		
	A84 0 453 234	10/1991	Europe		
	A85 0 487 155	05/1992	Europe		
	A86 0 587 380 A1	3/1994	Europe		
	A87 0587380	3/1994	Europe		
	A88 2 569 114	8/1984	France		
	A89 WO 87/05522	9/1987	PCT		
	A90 WO 89/05670	06/1989	PCT		
	A91 WO 90/07951	07/1990	PCT		
	A92 WO 93/17744	09/1993	PCT		
	A93 WO 95/30448	11/1995	PCT		

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	A94 GB 2 098 485	05/1984	Great Britain			
	A95 GB 2 268 286	09/1992	Great Britain			
	A96 185442	08/1966	Russia (USSR)			
	A97 812296	03/1981	Russia (USSR)			

EXAMINER INITIAL	OTHER ART (Including Author, Title, Date, Pertinent Pages, etc.)	
	A98	Hoover et al., "A Microspray Nozzle for Local Administration of Liquids or Suspensions to Lung Airways via Bronchoscopy," <i>Journal of Aerosol Medicine</i> , vol. 6, #2, 1993.
	A99	Wheeldon et al., <i>Aerosolized Endotoxin in Animals</i> , (1992).
	A100	Carlton, Graziano C.; Barker, Robert L.; Benua, Richard S.; Guy, Yvonne G; Airway Humidification With High-Frequency Jet Ventilation, <i>Critical Care Medicine</i> , vol. 13, No. 2, (1985).
	A101	Aiache, Jean-Marc; The Ideal Drug Delivery System: A Look into the Future, <i>Journal of Aerosol Medicine</i> , vol. 4, No. 4, 1991.
	A102	Wheeldon, Walker, Murphy, and Turner; <i>Aerosolized Endotoxin in Animals</i> , (1992).
	A103	Jager-Waldau, Reinhold; A Two-Phase-Flow Mechanical Spray Pump: A Possible Alternative To Propellant-Driven MDIs. <i>Journal of Biopharmaceutical Sciences</i> , 3(1/2), 077-084, (1992).
	A104	Niven, Ralph W.; Kacmarek, Robert M.; Brain, Joseph D.; Peterfreund, Robert A.; Small Bore Nozzle Extensions to Improve the Delivery Efficiency of Drugs from Metered Dose Inhalers: Laboratory Evaluation. <i>Am Rev Respir Dis</i> , vol. 147, pp. 1590-1594, 1993.
	A105	Taylor, Robert H.; Lerman, Jerrold; Chambers, Carole; Dolovich, Myrna; Dosing Efficiency and Particle-Size Characteristics of Pressurized Metered-Dose Inhaler Aerosols in Narrow Catheters. Presented at Annual Meeting American Society of Anesthesiologist, Las Vegas, Oct. 1990.
	A106	Hess, Dean; Inhaled Bronchodilators During Medical Ventilation: Delivery Techniques, Evaluation of Response, and Cost Effectiveness, <i>Respiratory Care</i> , vol. 39 No. 2, Feb. 1994.
	A107	Judson, Marc A.; Sahan, Steven A.; Mobilization of Secretions in ICU Patients, <i>Respiratory Care</i> , vol. 39 No. 3, Mar. 1994.
	A108	Copy of packaging for "ENDO-JET by Autovage", believed to have been published prior to June 14, 1994, 2 pages.
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